REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-69 are pending. Claims 1, 9, 12, 14, 16, 18, 19-21, 24, 25-28, 66 and 69 have been amended herein.

The Amendments

The specification was amended to insert a value for c, which was inadvertently omitted from Formula I and Formula II. Support therefor is in the specification, for example, page 17, line 20. As is evident from the specification and the formulas (e.g., Formulas I and V), c' corresponds to c. In addition, Formula I was amended to correct for the valency of N, as kindly noted in the Office Action. Formula III was amended to correct for the valency of N and to recite q is 1 to 5. Support therefor is in the specification, for example, Formula I, page 9, line 4.

Claim 1 was amended to delete the embodiments where R^2 is H, lower alkyl or a protecting group. Claim 1 was also amended to define "c" and to correct the valency of N.

Claim 9 was amended to define "c."

Claims 12, 16 and 19 were amended to refer to immunogenic carrier. Support therefor is in the specification, for example, page 11, lines 12-26.

Claims 14, 18, 20, 24 and 25 were amended to refer to particle label or particle immunogenic carrier. Support therefor is in the specification, for example, page 10, lines 7-13, and page 11, lines 19-20.

Claim 21 was amended to define "q" and to correct the valency of N.

Claims 26-28 were amended to refer to immunogenic carrier. Support therefor is in the specification, for example, page 11, lines 12-26.

Claims 66 and 69 were amended to define y' as 1.

Rejection under 35 U.S.C. 112

Claims 1-69 were rejected under the second paragraph of the above code section as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action observes that Claim 1 does not contain a definition of "c." Applicant believes that the amendment to Claim 1 in that regard obviates this ground of rejection.

The Office Action alleges that Claims 1, 6, 9, 13 and 21 recite the term "immunogenic carrier", "label" and/or "acid salts" and it is not clear what "immunogenic carrier" or "label" is encompassed by the terms as immunogenic carrier may include proteins, adjuvant and other non-protein substances and label may include various labeling agent such as fluorescein, cyanine, enzymes, radioactive substance, electrophoretic tag, etc. Therefore, concludes the Office Action, it is unclear what is intended by the terms immunogenic carrier or label.

Applicant respectfully traverses this ground of rejection. The terms "immunogenic carrier" and "label" are discussed in detail in the specification, for example, page 11, lines 12-26, and page 10, line 4, to page 11, line 11. In addition, these terms are understood by those skilled in the assay art.

Claims 1 was also rejected as indefinite because, asserts the Office Action, it is not clear what is encompassed by the term "acid salts". Applicant respectfully traverses this ground of rejection. The term "acid salts" is defined in the specification, for example, page 9, lines 30-32. Furthermore, the term is understood by the skilled artisan in the chemistry area.

The Office Action also observed that in Claim 1, when D is N, the valency of nitrogen in incorrect. Applicant submits that the amendment to Claim 1, and other claims with the same error, in that regard obviates this ground of rejection.

Claims 1, 9 and 21 were rejected for recitation of the term "protecting group". The Office Action contends that it is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, concludes the Office Action, these claims are vague and indefinite for not clearly defining the protecting group. First of all, the term is used in the claims for a substituent on either an -O- or -N- functionality. Second, the specification discusses in detail what is meant by the term. See, for example, page 7, lines 19-29. Finally, the term is well-known to those skilled in the art.

The Office Action asserts that the phrase "said poly(amino) acid is an immunogen" is confusing in claims 12, 15, 19 and 26-28. It is not clear, continues the Office Action, whether the poly(amino) acid conjugated with the compound of formula II is an immunogenic carrier or it itself acts as an immunogen (epitope). Applicant believes that the amendment to the above claims in that regard obviates this ground of rejection.

The term "particle" in Claims 14 and 25, argues the Office Action, is unclear and therefore indefinite as this is a relative term and mere perception of a person looking at it. The Office Action asserts that this term is subjective and, therefore, does not establish any metes and bounds. Applicant submits that the amendment to the above claims, and other claims reciting the word "particle," obviates this ground of rejection. The term is understood by those skilled in the assay art as evidenced by the numerous particle-based assay formats some of which are mentioned in the specification, for example, page 27, line 20, to page 28, line 2.

With respect to claims 44, 49, 63 and 66, the Office Action alleges that it is not clear whether "antibody" used in the method is raised against a compound of what formula, i.e., against what hapten immunogen conjugate? In each of the above claims, a label conjugate in accordance with embodiments of the present invention is recited. Consequently, the claim language is intended to include any antibody specific for the designated compound since the patentability of the methods is determined by the label conjugate and not the antibody. In addition, antibodies are discussed in detail in the specification, for example, page 23, line 23, to page 25, line 11.

The Office Action contends that it is not clear what is encompassed by the term "analog" in Claims 54, 59, 68 and 69. The term "analog" is defined in the specification, for example, page 25, lines 12 to 26.

Rejection under 35 U.S.C. 102

Claims 1-20, 26-27, 29-30, 32-39, 49-53, 59-63, 66, 67 and 69 were rejected under 35 U.S.C. 102(a) as being anticipated by Hui, *et al.* (EP 1,340,981 A2) (Hui). The reference discloses compounds including haptens, intermediates, and immunogens that are useful in the production of antibodies specific for the methylenedioxy class of amphetamine derivatives.

Without acquiescing in the rejection of the aforementioned claims, Applicant

submits that amended Claim 1, and claims depending therefrom, are patentable over Hui. The reference does not disclose or suggest the compounds of the present claims. In Hui, J is defined as 1-15 carbon atoms and 0-6 heteroatoms, M is selected from the group M is selected from the group consisting of --O--, --CO--, --NR^4--, --S--, --C(=NH)O--, --NH(CO)--, --NH(CO)NH--, --NH(CS)--, --NH(CS)NH--, --O(CO)NH--, --NH(C=NH)--, and maleimidothioether, wherein R^4 is selected from the group consisting of hydrogen and an alkyl group. T is selected from the group consisting of hydrogen, a hydroxyl, a leaving group, a macromolecular carrier, and a label.

The aforementioned J-M-T moiety of the reference does not anticipate or suggest the moieties claimed in Claim 1. For example, Hui does not disclose or suggest the $(CH_2)_b$ of the $-(CH_2)_aC(O)(CH_2)_bSR^3$ moiety of Claim 1. Furthermore, Hui does not disclose or suggest the moiety $-(CH_2)_aC(O)(CH_2)_bS(CH_2)_cC(O)NR^4R^5$ when R^3 is $(CH_2)_cC(O)NR^4R^5$. In particular, for example, the reference does not provide for or suggest the $(CH_2)_bS(CH_2)_cC(O)NR^4R^5$ moiety of the above. For reasons similar to those above, the reference does not disclose or suggest the moiety $(A)_d(Q)_n$ of Claim 1 wherein Q is H or -$(CH_2)_eCH(R^8)(CH_2)_fOC(O)(CH_2)_gR^9$ being H only when d is 1 wherein A is -$C(O)(CH_2)_hC(O)NR^{10}((CH_2)_jO(CH_2)_kO)_m(CH)_2NR^{11}$-.

For reasons much the same as those indicated above, Hui does not disclose or suggest Claim 9 and those claims depending therefrom.

Hui does not disclose or suggest the moiety of Claim 49 and those claims depending therefrom. The moiety of Claim 49, namely, -$C(O)(CH_2)_a$-$S(CH_2)_c$-$C(O)NH$-, is not covered by or suggested by the J-M-T group of the reference.

For reasons substantially similar to those with respect to the rejection of Claim 49, Claims 59, 66 and 69, and those claims depending therefrom, are not disclosed or suggest by Hui.

The Office Action makes the following statement: "It is noted that the claimed compounds wherein R^{19}, R^{20}=cycle and R^1, R^2 =H or alkyl is anticipated by MDA, MDMA or MDEA (see Hui et al, paragraph [0002])." Applicant submits that the amendments to the claims obviate this situation.

Claims 1-20, 26-27, 29-30, 32-39, 49-53, 59-63, 66-67 and 69 were rejected under 35 U.S.C. 102(b) as being anticipated by Rouhani, *et al.* (GB

2361473 A) (Rouhani). Rouhani discusses ecstasy-class analogs and the use of same in detection of ecstasy-class compounds. The reference discloses certain immunogens for generating antibodies and also discloses certain enzyme conjugates.

Without acquiescing in the rejection of the aforementioned claims, Applicant submits that amended Claim 1, and claims depending therefrom, are patentable over Rouhani. The reference does not disclose or suggest the compounds of the present claims. In Rouhani, Q is selected from the group consisting of hydrogen, a first moiety, a substituted derivative of the first moiety, and L^1_n-Z, where the first moiety is selected from the group consisting of a straight moiety, a branched moiety, a cyclic moiety, and combinations thereof, and the first moiety has a backbone of m backbone atoms where m is an integer ≥ 1, with the m backbone atoms independently selected from the group consisting of carbon, nitrogen, oxygen, sulfur, a non-substitutable halide, and combinations thereof; where L^1_n is selected from the group consisting of a second moiety and a substituted derivative of the second moiety; where the second moiety is selected from the group consisting of a straight moiety, a branched moiety, a cyclic moiety, and combinations thereof, and the second moiety has a backbone of n backbone atoms where n is an integer ≥ 0, with the n backbone atoms independently selected from the group consisting of carbon, nitrogen, oxygen, sulfur, a non-substitutable halide, and combinations thereof; and where Z is a moiety capable of chemically bonding, either directly or indirectly, with an immunogenic carrier, a detectable label, or a solid capture vehicle.

Rouhani indicates that the phrase "a linker containing at least one carbon atom" is meant to refer to any generic linking group between two other groups, e.g., a linker between hapten and protein, or a linker between hapten and a functional group suitable for attachment to another molecule, which contains at least one carbon atom. The linker group may be a C_1-C_{20} hydrocarbon chain containing zero to ten heteroatoms selected from the group consisting of N, O, and S, and which contains at least as many carbon atoms as heteroatoms. Examples of such generic linking groups indicated in the reference include --O--$(CH_2CH_2O)_n$--, where n is an integer between 1 and 10 (i.e., a polyethylene glycol linker); --CH_2CH_2-phenyl-CH_2CH_2-- (in ortho, meta, or para connection); --CH_2CH_2--CONH--CH_2CH_2-- (i.e., an amide linkage), --C(=O)--CHS--NH-- (i.e., an amino acid linker, where S is a naturally or non-naturally occurring amino acid side chain) or any straight-chain,

branched, cyclic, or combination of straight-chain, branched, or cyclic linking group that will serve as a covalent linkage between the two other groups. A further example is C_1-C_{20} alkyl groups.

The aforementioned generic recitation of a group of atoms selected from the group consisting of certain atoms does not anticipate or suggest the moieties claimed in Claim 1. The disclosure of the reference is no more than an invitation for one to invent linking groups. Furthermore, the specific disclosure of Rouhani of certain linking groups does not include those in the present claims. For example, Rouhani does not disclose or suggest the $(CH_2)_a$ of the $-(CH_2)_aC(O)(CH_2)_bSR^3$ moiety of Claim 1. Furthermore, Rouhani does not disclose or suggest the moiety $-(CH_2)_aC(O)(CH_2)_bS(CH_2)_cC(O)NR^4R^5$ when R^3 is $(CH_2)_cC(O)NR^4R^5$. In particular, for example, the reference does not provide for or suggest the $(CH_2)_bS(CH_2)_cC(O)NR^4R^5$ moiety of the above. For reasons similar to those above, the reference does not disclose or suggest the moiety $(A)_d(Q)_n$ of Claim 1 wherein Q is H or $-(CH_2)_eCH(R^8)(CH_2)_fOC(O)(CH_2)_gR^9$ being H only when d is 1 wherein A is $-C(O)(CH_2)_hC(O)NR^{10}((CH_2)_jO(CH_2)_kO)_m(CH)_2NR^{11}-$.

For reasons much the same as those indicated above, Rouhani does not disclose or suggest Claim 9 and those claims depending therefrom.

Rouhani does not disclose or suggest the moiety of Claim 49 and those claims depending therefrom. The moiety of Claim 49, namely, $-C(O)(CH_2)_{a'}S(CH_2)_{c'}C(O)NH-$, is not covered by or suggested by the generic or specific teachings of the reference.

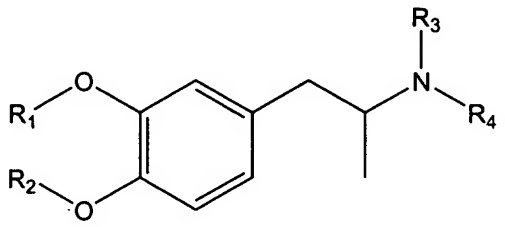
For reasons substantially similar to those with respect to the rejection of Claim 49, Claims 59, 66 and 69, and those claims depending therefrom, are not disclosed or suggest by Rouhani.

Double Patenting

Claims 1-20, 26-27, 29-30, 32-39, 49-53, 59-63, 66-67 and 69 were provisionally rejected under the "judicially created doctrine of double patenting" over claims 1-29, 31, 33, 34 and 37 of copending Application No. 10/736,005 (the '005 application). The Office Action alleges that Claims 1-29, 31, 33, 34 and 37 of the referenced patent are drawn to compounds of formula I and II, which are equivalent to formula I and II of the present application when W is H and R_{19} and R_{20} are lower alkyl or taken

together to form a ring. Furthermore, continues the Office Action, the referenced claims are drawn to methods and kits comprising the same steps, ingredients and essentially the same composition as claimed in the cited claims of instant application. The Office Action asserts that the referenced claims disclose immunogenic carrier, label, antibody, method and kit for immunoassay detection and quantitation of ecstasy compounds, which also anticipates cited claims of the instant invention. Compare, for example, invites the Office Action, formula I of claim 1 of 10/736,005 wherein R^1, R^2, R^3, R^4=alkyl with formula I of claim I of 10/736,018 wherein R^{19}, R^{20}, R^1, R^2=alkyl.

The '005 application is directed in some embodiments to compounds of the formula:



Formula I

wherein: R^1 is H, lower alkyl, a protecting group, or is taken together with R^2 to form a ring,

R^2 is H, lower alkyl, $-(CH_2)_nSCH_2C(O)R^6$ or $-(CH_2)_nC(SO_2R^6)=CH_2$, or is taken together with R^1 to form a ring,

R^3 and R^4 are independently H or lower alkyl or a protecting group, or, when R^1 is taken together with R^2 to form a ring, at least one of R^3 or R^4 is $-C(O)(CH_2)_nR^5$, $-C(O)(CH_2)_nNHC(O)R^5$, $-C(O)(CH_2)_nNHC(O)(CH_2)_nSR^5$, $-(CH_2)_nC(SO_2R^5)=CH_2$, $-(CH_2)_nSCH_2C(O)R^5$, or $-(CH_2)_nC(SO_2R^5)=CH_2$, or when R^1 is not taken together with R^2 to form a ring, at least one of R^1 and R^2 is not H or lower alkyl or a protecting group,

R^5 is H, -OH, -SH, -O-lower alkyl, halogen, NH_2, -succinimidyl, -maleimidyl, immunogenic carrier, or label,

R^6 is H, -OH, -SH, -O-lower alkyl, halogen, NH_2, -succinimidyl, -maleimidyl, immunogenic carrier, or label, and

n is an integer from 1 to 5,

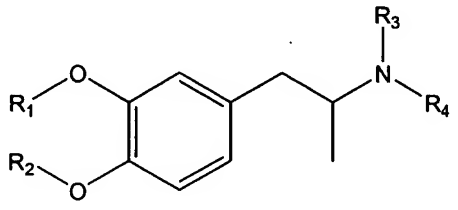
and including acid salts thereof.

The claims of the present application do not anticipate or suggest the compounds of the '005 application or vice versa. The claims of the two applications are not claiming the same subject matter. The claims of one application could be literally infringed without infringing the claims of the other application (assuming the applications issue as patents). Furthermore, the linking groups comprise different functionalities, not suggested by one another. Finally, the amendments to the instant claims preclude the specific example set forth in the Office Action. As amended, R^2 cannot be alkyl.

Claims 1-20, 26-27, 29-30, 32-39, 49-53, 59-63, 66-67 and 69 were provisionally rejected under the "judicially created doctrine of double patenting" over claims 1-24, 26, 28, 29 and 32 of copending Application No. 10/736,004 (the '004 application). The Office Action alleges that Claims 1-24, 26, 28, 29 and 32 of the referenced patent are drawn to a compounds of formula I and II, which are equivalent to formula I and II of the present application when W is H and R_{19} and R_{20} are lower alkyl or taken together to form a ring. Furthermore, continues the Office Action, the referenced claims are also drawn to methods and kits comprising the same steps, ingredients and essentially the same composition as claimed in the cited claims of instant application. The Office Action asserts that the referenced claims disclose immunogenic carrier, label, antibody, method and kit for immunoassay detection and quantitation of ecstasy compounds, which also anticipates cited claims of the instant invention. Compare, for example, invites the Office Action, formula I of claim 1 of 10/736,005 wherein R^1, R^2, R^3, R^4=alkyl with formula I of claim I of 10/736,018 wherein R^{19}, R^{20}, R^1, R^2=alkyl.

Claim 1 of the '004 patent application recites as follows:

A compound of the formula:



Formula I

wherein: R^1 is H, lower alkyl, a protecting group, or is taken together with R^2 to

form a ring,

R^2 is H, lower alkyl, a protecting group, $-(CH_2)_nC(O)R^6$ or $-(CH_2)_nR^6$ or is taken together with R^1 to form a ring,

R^3 and R^4 are independently H or lower alkyl or a protecting group, or, when R^1 is taken together with R^2 to form a ring, at least one of R^3 or R^4 is $-(CH_2)_nC(O)R^5$ or $-(CH_2)_nR^5$, or when R^1 is not taken together with R^2 to form a ring, at least one of R^1 and R^2 is not H or lower alkyl or a protecting group,

R^5 is H, -OH, -SH, -O-lower alkyl, halogen, NH_2, -succinimidyl, -maleimidyl, immunogenic carrier, or label,

R^6 is H, -OH, -SH, -O-lower alkyl, halogen, NH_2, -succinimidyl, -maleimidyl, immunogenic carrier, or label, and

n is an integer from 1 to 5,

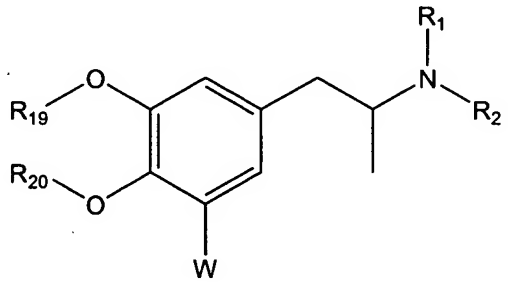
with the proviso that, when R^1 is CH_3, R^2 is not $-CH_2C(O)R^6$, and

with the proviso that, when R^1 is taken together with R^2 to form a ring and when only one of R^3 and R^4 is H or lower alkyl and the other of R^3 and R^4 is $-(CH_2)_nC(O)R^5$, R^5 is a protein,

and including acid salts thereof.

Claim 1 of the present application as amended above recites as follows:

A compound of the formula:



Formula I

wherein: R^{19} is lower alkyl or is taken together with R^{20} to form a ring, which may be a five- or six-member ring, usually a five-member ring;

R^{20} is lower alkyl, or is taken together with R^{19} to form a ring as discussed above,

R^1 is H or lower alkyl,

R^2 is

(a) $-(CH_2)_aC(O)(CH_2)_bSR^3$, wherein a is 0 to 5, b is 1 to 5 and R^3 is H or lower alkyl or $(CH_2)_cC(O)NR^4R^5$ wherein c is 1 to 5, R^4 is H or lower alkyl and R^5 is H, an immunogenic carrier or a label, or

(b) $(A)_d(Q)_n$ wherein Q is H or $-(CH_2)_eCH(R^8)(CH_2)_fOC(O)(CH_2)_gR^9$ being H only when d is 1 wherein A is $-C(O)(CH_2)_hC(O)NR^{10}((CH_2)_jO(CH_2)_kO)_m(CH)_2NR^{11}-$, d is 0 or 1, n is 0 or 1 wherein one of d or n is 1, h is 1 to 5, R^{10} is H or lower alkyl, j is 1 to 5, k is 1 to 5, m is 1 to 3, R^{11} is H or lower alkyl, e is 1 to 5, R^8 is OH or H, f is 1 to 5, g is 0 to 5, and R^9 is H, an immunogenic carrier or a label;

W is H or JR^{14} being H when R^2 is other than H or lower alkyl, wherein

J is O or S,

R^{14} is H, lower alkyl, a protecting group, or $-(CH_2)_rC(O)NR^{15}(CH_2)_s(D)_tR^{16}$, wherein r is 1 to 5, R^{15} is H or lower alkyl, s is 1 to 5, D is S, O or NH, t is 0 or 1 being 0 when R^{16} is maleimidyl or succinimidyl, R^{16} is H, maleimidyl, succinimidyl, or $-(CH_2)_qC(O)NR^{17}R^{18}$,

q is 1 to 5,

R^{17} is H or lower alkyl,

R^{18} is H, lower alkyl, an immunogenic carrier or label,

and including the acid salts thereof.

The claims of the present application do not anticipate or suggest the compounds of the '004 application or vice versa. The linking groups comprise different functionalities, not suggested by one another. The claims of one application could be literally infringed without infringing the claims of the other application (assuming the applications issue as patents). The claims of the two applications are, therefore, patentably distinct.

The Office Action further argued that there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application and referred to *In re Schneller,* 397 F.2d 350, 158 USPQ 210 (CCPA 1968) and MPEP § 804. Applicant cannot determine what rejection is set forth based on *In re Schneller* and whether such rejection has been approved by the Technology Center Director as required by MPEP § 804.

The double patenting rejections mentioned above are not maintainable. In any

event the conflicting claims have not been patented and, thus, any consideration of the need for a terminal disclaimer is premature.

Conclusion

Applicant has demonstrated that Claims 1-69 satisfy the requirements of 35 U.S.C. 112. Claims 1-20, 26, 27, 29, 30, 32-39, 49-53, 59-63, 66, 67 and 69 satisfy the requirements of 35 U.S.C. 102. Claims 21-25, 28, 31, 40-48, 54-58, 64, 65 and 68 were not rejected over the prior art. Furthermore, the present claims are patentably distinct over the claims of the above-mentioned co-pending applications. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

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